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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/537,647 | 12/28/2005 | Koen Vandenbroeck | 08830-0344US1 | 6304 |

23973 7590 03/18/2008

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| EXAMINER | |
|---|---|
| MITCHELL, LAURA MCGILLEM | |
| ART UNIT | PAPER NUMBER |
| 1636 | |
| MAIL DATE | DELIVERY MODE |
| 03/18/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,647 | VANDENBROECK ET AL. | |
| | Examiner | Art Unit | |
| | LAURA M. MITCHELL | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33 and 36-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33, 36 and 37-41* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11 and 16-25, drawn to an expression vector comprising a sequence encoding a subunit of a dimeric form of interleukin under transcriptional control of an ecdysone-inducible promoter and a cell line comprising that vector.

Group II, claim(s) 12-15 and 27, drawn to a method of producing a cDNA encoding a subunit of a dimeric form of interleukin and a method of producing an expression vector.

Group III, claim(s) 26, drawn to a method of making a cell line capable of producing a dimeric interleukin.

Group IV, claim(s) 28-30, drawn to a method of screening a compound for the ability to inhibit dimer assembly and secretion of dimeric interleukin.

Group V, claim(s) 31, drawn to an inhibitor of dimer assembly and secretion of dimeric interleukin.

Group VI claim(s) 32-33, 36 and 38-41, drawn to a method of treatment for a disease having a pathogenesis which includes endogenous production of any of IL-12, IL-23 or IL-27 comprising administering an ER calcium perturbation reagent that is selected from the compounds of Formula I.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The species lack unity of invention and lack a special technical feature that defines a contribution over the prior art because the Applicants' claimed expression vector was known in the prior art. Barski et al (U.S. Patent No. 6,630,324, filed 7/26/2000) teach vectors for protein

expression. Barski et al teach that embodiments of the expression vector can comprise and ecdysone-inducible promoter expression system (see column 24, lines 36-50, in particular). Barski et al claim an embodiment in which the expression vector comprises a sequence encoding a p35 and the p40 subunit of IL-12 (see column 62, lines 46-54, in particular), which meets the limitation of an expression vector comprising a DNA encoding a subunit of a dimeric form of interleukin under the control of an ecdysone-inducible promoter.

The technical feature of Group I is an expression vector comprising an ecdysone-inducible promoter operably linked to a gene encoding a subunit of a dimeric form of interleukin. The expression vector of Group I can be used for multiple methods and is not required for any one particular method. For example, the expression vector comprising a gene encoding a subunit of a dimeric form of interleukin can be used for making a cell line or could be used in a method of *in vitro* translation.

The technical feature of Group II is a method of producing a cDNA encoding a subunit of a dimeric form of interleukin and a method of making an expression vector, which comprises the step of ligating a digested interleukin cDNA into an ecdysone-inducible expression vector, which is not found in the methods of Groups III-IV and VI.

The technical feature of Group III is a method of making a cell line capable of producing a dimeric interleukin, which comprises the step of transfecting a host cell with an expression vector, which is not found in the methods of Groups II, IV and VI.

The technical feature of Group IV is a method of screening a compound for the ability to inhibit dimer assembly, which comprises the step of incubating a cell culture with a candidate compound, which is not found in the methods of Groups II-III and VI.

The technical feature of Group V is an inhibitor of dimer assembly. The inhibitor of dimer assembly can be used in multiple methods and can be used for another purpose besides for treatment of a subject with a disease such as for *in vitro* metabolic testing.

The technical feature of Group VI is a method of treatment of disease, which comprises the step of treating a subject with an ER calcium perturbation reagent which is not found in the methods of Groups II-IV.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The compound of Formula I as pictured in claim 41 wherein:

**A =** substituent selected from partially unsaturated or unsaturated heterocyclyl or partially unsaturated or unsaturated carbocyclic rings.

**$R^1$ =** a substituent selected from hetercyclyl, cycloalkyl, cycloalkenyl and aryl, wherein $R^1$ is optionally substituted at a substitutable position with one or more radicals selected from alkyl, haloalkyl, cyano, carboxyl, alkoxycarbonyl, hydroxyl, hydroxyalkyl, amino, alkylamino, arylamino, nitro, alkoxyalkyl, alkylsulfinyl, halo, alkoxy and alkylthio.

**$R^2$ =** methyl or amino; and wherein $R^3$ is a radical selected from hydrido, halo, alkyl, alkenyl, oxo, cyano, carboxyl, cyanoalkyl, heterocyclyloxy, alkyloxy, alkylthio, alkylcarbonyl, cycloalkyl, aryl, haloalkyl, heterocyclyl, cycloalkenyl, aralkyl, hetrocyclylalkyl, acyl, alkythioalkyl, hydroxyalkyl, alkoxycarbonyl, arylcarbonyl, aralkylcarbonyl, aralkenyl, alkoxyalkyl, arylthioalky, aryloxyalkyl, aralkylthioalky, aralkoxyalkyl, alkoxyaralkoxyalkyl, alkoxycarbonalkyl, aminocarbonyl, aminocarbonylalkyl, alkyaminocarbonyl, N-arylaminocarbonyl, N-alkyl-N-arylaminocarbonyl, alkylaminocarbonylalkyl, carboxyalkyl, alkylamino, N-arylamino, N-aralkylamino, N-alkyl-N-aralkylamino, N-alkyl-N-arylamino, aminoalkly, alkylaminoalkyl, N-arylaminoalkyl, N-aralkylaminoalkyl, N-alkyl-N-aralkylaminoalky, N-alkyl-N-arylaminoalkyl, aryloxy, aralkoxy, arylthio, aralkylthio, alkylsulfinyl, alkylsulfonyl,

aminosulfonyl, alkylaminosulfonyl, N-arylaminosulfonyl, arylsulfonyl, N-alkyl-N-arylaminosulfonyl; or a pharmaceutically-acceptable salt thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 33, 36, 38-41 all use the compound.

The following claim(s) are generic: 33 and 36.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species lack unity of invention and lack a special technical feature that defines a contribution over the prior art because the Applicants' claimed compound was known in the prior art as Celebrex, a COX-2 inhibitor, and is taught by US Patent No 5,972,986.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA M. MITCHELL whose telephone number is (571)272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura M. Mitchell
Examiner
3/9/2008

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636